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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/813,307

03/30/2004

David A. Dinsmoor

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

04/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/813,307	Applicant(s) DINSMOOR ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 17-19, 21-32, 41, 42, 44-47, 67 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 67 and 68 is/are allowed.
- 6) ☒ Claim(s) 1-3, 17-19, 21-31, 41, 42 and 44-47 is/are rejected.
- 7) ☒ Claim(s) 4, 5 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/2/2009 has been entered.

Acknowledgments

1. This office action is in response to the reply filed on 4/2/2009.
2. In the reply, the Applicant amended claims 1, 29.
3. Claims 67-68 are previously indicated as allowed and claims 4-5, 32 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
4. Claims 1-5, 17-19, 22-32, 41-42, 44-47, 67-68 are pending.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 17, 18, 24-31, 41, 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Cartledge et al (7175660).

In reference to claims 1 and 29, Cartledge et al discloses a medical device comprising: a device housing (Fig 1; col 4, Ins 26-36, Ins 61-65; col 5, Ins 1-11; col 11, Ins 54-64; col 14, Ins 3-12; 34-col 16, Ins 63) sized for introduction into and residence completely within the body lumen; a fixation mechanism (adjustment means – may be a variety of elements – col 15, Ins 47-57) to attach the device housing to a surface within the body lumen (see above citations); and a controlled detachment mechanism (adjustment mechanism), mechanically actuated to selectively self-detach the device housing from the surface of the body lumen without endoscopic intervention (adjustment mechanism controls the means to remotely change the shape/size and including complete detachment and removal from the body; see above citations; and response to arguments below); and a controller (remote control external from body) responsive to a control signal (electronic, magnetic, uv light etc.. see above citations) and external to the body lumen, wherein the controller activates the controlled detachment mechanism (see above citations), and wherein the medical device remains completely within the body lumen until after the device is detached from the surface (see above citations). Additionally, see below in Response to Arguments.

In reference to claim 2 and 30, see (adjustment means – may be a variety of elements – col 15, Ins 47-57); claim 17, 18, 41, see (adjustment mechanism may be electromechanical motors or other electrically controlled and powered systems; see

above citations); claim 24-25 and 45, see (col 14, Ins 34-col 16, Ins 63); for claim 26-27 and 46, see (above citations and col 4, Ins 65-67); and for claims 28 and 47, see (above citations).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 3 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartledge et al in view of Kilcoyne et al (6689056). Cartledge et al discloses the invention substantially as claimed except for expressly disclosing vacuum pressure to draw the tissue into the lumen. Kilcoyne et al teaches that it is known to have vacuum pressure to drawn tissue into the lumen (col 10, Ins 24-26) for the purpose of grabbing tissue to attach the attachment mechanism. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Cartledge et al with the vacuum pressure as taught by Kilcoyne et al for the purpose of grabbing tissue to attach the attachment mechanism.

9. Claims 19, 22-23, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartledge et al in view of Imran et al (6535764). Cartledge et al discloses the invention substantially as claimed except for expressly disclosing the power source including an inductive coupling to generate power for the detachment

mechanism. Imran et al teaches that it is known to have the power source including an inductive coupling to generate power for activating a detachment mechanism (col 22, lns 8-30, col 23, lns 20-33) for the purpose of remotely generating power. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Cartledge et al with the power generator as taught by Imran et al for the purpose of remotely generating power to power a detachment mechanism.

Response to Arguments

Applicant's arguments filed 4/2/2009 have been fully considered but they are not persuasive.

The Applicant argues that Cartledge does not disclose that the device can be selectively detached without endoscopic intervention.

In response to the applicant's arguments the Examiner respectfully disagrees and notes that Cartledge explicitly discloses that the adjustment means may be contained within the implant and adjusted remotely (e.g. remote control adjustment) without endoscopic intervention and such adjustment means is capable of removal from the body (col 4, lns 25-36 – additionally, see Fig 1; col 4, lns 26-36, lns 61-65; col 5, lns 1-11; col 11, lns 54-64; col 14, lns 3-12; 34-col 16, lns 63 and col 15, lns 47-57). By remotely controlling the adjustment means the device can be detached from the body to allow for removal from the body. See:

In addition, such an adjustable prosthetic implant according to the present invention could be coupled with an adjustment means capable of being placed in the subcutaneous or other anatomic tissues within the body, such that remote

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adjustments could be made to the implant during physiologic function of the implant. Such an adjustment means might be capable of removal from the body, or might be retained within the body indefinitely for later adjustment. (col 4, lns 26-36)

In still other embodiments, the adjustment mechanism may be driven by implanted electromechanical motors or other systems, which may be remotely controlled by electronic flux or other remote transcutaneous or percutaneous methods. (col 14, lns 7-12)

In some embodiments as contemplated by the present invention, an adjustment tool may be removably or permanently attached to the adjustment mechanism and disposed to impart motion to the adjustment mechanism and, in turn, to the adjustment means to increase or decrease the anatomic effect of the implant on the native recipient site. In alternate embodiments according to the present invention, micromotor arrays with one or more micro-electromechanical motor systems with related electronic control circuitry may be provided as an adjustment means, and may be activated by remote control through signals convey by electromagnetic radiation or by direct circuitry through electronic conduit leads which may be either permanently or removably attached to said micromotor arrays. (col 16, lns 25-39)

Endoscopic intervention is clearly not required for detachment. The rejection is maintained.

Allowable Subject Matter

10. Claims 67-68 are allowed.

11. Claims 4-5, 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is

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(571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767